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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,681	02/23/2004	Chein-Shyong Su	U 015044-9	1963

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EXAMINER	
VESTAL, REBECCA M	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,681	SU ET AL.	
	Examiner	Art Unit	
	R. Michelle Vestal	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☒ Claim(s) *24 and 25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/01/04, 4/08/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the active reaction layer of claim 1 must be shown or the feature canceled from the claim. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 15 cites the limitation that the reaction catalyst is a non-bio catalyst. This limitation has not been disclosed in the specification.

Claim Objections

Claims 24 and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The manner in which the insulating material is attached to the electrode layer fails to provide a positive structural limitation to the claimed electrochemical biosensor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 recites the limitations 'the working electrode, the reference electrode and the auxiliary electrode" in lines 9-10. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-14, 16-20, 22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,488,828 to Bhullar et al. in view of U.S. Patent Number 5,120,420 to Nankai et al., referred to hereafter as "Bhullar" and "Nankai," respectively.

Regarding claim1, Bhullar discloses an electrochemical biosensor (Col. 1, lines 5-6), comprising:

an insulating base plate (Fig. 11, **12**);

an electrode layer comprising electrodes having a reference electrode and at least one electrode (Fig. 11, **16** and **18**), and two contact ports being adapted to connect a measuring device, and being formed on said insulating base plate (Col. 3, lines 3-11);

a middle insulating layer being applied on said conductive wire and said electrode layers without covering said electrodes and said contact ports (Fig. 11, **114**), said insulating layer comprising an opening formed therein, and said opening being opposed to said electrodes of said insulating base plate (Fig. 11, **140**);

an active reaction layer having substances of reactant, reaction catalyst, mediator and surfactant (Fig. 11, **120**) spread between the starting point of said opening and the surface of said electrodes; and

an upper cover (Fig. 10 or 11, **124**) opposing to an upwardly extended closed space formed within said insulating layer and being in contact above said insulating layer (Fig. 10 or 11, **170**), said opening forming a capillary inflow area and said closed space being positioned opposing to one end of the inflow area.

The recitation that the electrode layer is "formed ... by screen printing" does not impart any positive structural limitation on the electrochemical biosensor and therefore, has not been given any patentable weight.

Bhullar does not disclose expressly that a layer of electrically conductive wires is disposed on said insulating base plate with an electrode layer formed on said wires.

Nankai discloses an electrochemical biosensor comprising a layer of electrically conductive wires disposed on an insulating base plate and a layer of electrodes formed on said wires by screen printing (Col. 4, lines 51-55).

Bhullar and Nankai are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the layer of electrically conductive wires of Nankai in the electrochemical biosensor of Bhullar because the conductive wires are useful for forming a good electrical contact with the measuring device or meter.

Therefore, it would have been obvious to combine Bhullar with Nankai to obtain the invention as specified in claim 1.

Bhullar discloses the limitations of claim 2, wherein said biosensor is a bi-electrode system comprising a working electrode and a reference electrode (Col. 3, lines 3-11).

Bhullar discloses the limitations of claim 3, wherein said biosensor is a tri-electrode system comprising a working electrode, a reference electrode and an auxiliary electrode (Col. 3, lines 3-11).

Bhullar discloses the limitations of claim 4, wherein said opening is U-shaped (Fig. 11, **140**).

Bhullar discloses the limitations of claim 6, wherein the insulating base plate is made of material selected from the group consisting of polyester, polyimide, and polyvinylchloride (Col. 2, lines 32-35).

Bhullar discloses the limitations of claims 7 and 9-13, wherein said electrode layer or said layer of electrically conductive wires is silver, gold, carbon or platinum (Col. 2, lines 48-57).

Bhullar discloses the limitations of claims 14 and 16, wherein said reaction catalyst is a biocatalyst or enzyme (Table 1).

Bhullar discloses the limitations of claims 19 and 20, wherein the length and width of said opening is between 2 and 8 mm and between 0.5 and 5 mm, respectively (Col. 9, lines 26-30).

Bhullar discloses the limitations of claim 22, wherein sample can be filled and detected when it is introduced above said working electrode and said auxiliary electrode (Col. 7, line 59-Col. 8, line 60).

Bhullar discloses the limitations of claim 25, wherein said insulating material is adhered on said conductive wire and said electrode layers (Col. 3, lines 24-26).

Regarding claim 8, Bhullar discloses a biosensor comprising a reference electrode (Col. 3, lines 5-11).

Bhullar does not disclose expressly that the reference electrode comprises silver chloride.

Nankai discloses a biosensor, wherein said layer of electrically conductive wires is silver chloride (Col. 10, lines 8-17).

Bhullar and Nankai are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a reference electrode comprising silver chloride of Nankai in the electrochemical biosensor of Bhullar because the accuracy of the measurements obtained can be further improved by incorporating the silver/silver chloride reference electrode, as taught by Nankai (Col. 10, lines 8-10).

Therefore, it would have been obvious to combine Bhullar with Nankai to obtain the invention as specified in claim 8.

Regarding claims 17 and 18, Bhullar discloses that the thickness of the middle insulating layer defines the height of the test chamber (Col. 9, lines 26-29).

Bhullar does not disclose expressly what the thickness of the insulating layer is.

Nankai discloses a biosensor, wherein the thickness of said middle insulating layer is between 20 and 400 μm (Col. 5, lines 11-12) or between 50 and 200 μm (Col. 12, lines 43-54).

Bhullar and Nankai are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the middle insulating layer with a thickness between 20 and 400 μm or between 50 and 200 μm of Nankai in the electrochemical biosensor of Bhullar because such a thickness would ensure that only a small sample volume would be necessary for measurement, but in sufficient quantity to ensure high accuracy and rapid response, as taught by Nankai (Col. 2, lines 62-68).

Therefore, it would have been obvious to combine Bhullar with Nankai to obtain the inventions as specified in claims 17 and 18.

Regarding claims 24 and 26, Bhullar does not disclose expressly that the insulating material is insulating paste applied by screen printing.

Nankai discloses an electrochemical biosensor, wherein said insulating material is insulating paste (Col. 4, lines 58-60) and is applied on said conductive wire and said electrode layers by screen printing (Col. 4, lines 58-60).

Bhullar and Nankai are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to utilize insulating paste as the insulating material of Nankai in the electrochemical biosensor of Bhullar because screen printing an insulating paste is a cheap and effective way of forming an insulating layer which can define a space for a specific quantity of sample solution for analysis, as taught by Nankai (Col. 3, lines 31-38).

Therefore, it would have been obvious to combine Bhullar with Nankai to obtain the inventions as specified in claims 24 and 26.

Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar and Nankai as applied to claim 1 above, and further in view of U.S. Patent Number 6,793,802 to Lee et al., referred to hereafter as "Lee."

Regarding claims 5 and 21, Bhullar (Col. 3, lines 21-24) and Nankai (Fig. 4, **7**, Fig. 8, **7**, Fig. 10, **7**, Fig. 12, **7** and Fig. 13, **7**) disclose a variety of shapes and configurations of the opening in the middle insulating layer and that the volume of sample solution required for analysis is small (Nankai, Col. 2, lines 62-68).

Neither Bhullar nor Nankai disclose expressly that the opening in the middle insulating layer is T-shaped or that the volume of the closed space opposing the middle insulating layer is between 0.5 and 4 μL.

Lee discloses an electrochemical biosensor and a method of making the biosensor (Col. 16, lines 38-50), wherein the opening in the middle insulating layer is T-shaped (Fig. 9B), with a length and width of the opening between 2 and 8 mm and between 0.5 and 5 mm, respectively (Fig. 5A) and the volume of the closed space opposing to the middle insulating layer is between 0.5 and 4 μL (Col. 13, lines 43-45).

Bhullar, Nankai and Lee are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute the T-shaped opening in and the small volume of the closed space of the middle insulating layer of Lee in the electrochemical biosensor of Nankai because the T-shape sample area improves the sample application and measuring

properties of the biosensor, as taught by Lee (Col. 2, lines 64-66) to ensure a quick and uniform distribution of sample, especially a small volume of sample (Col. 12, lines 38-40).

Therefore, it would have been obvious to combine Bhullar, Nankai and Lee to obtain the inventions as specified in claims 5 and 21.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar and Nankai as applied to claim 1 above, and further in view of U.S. Patent Application Publication Number US 2002/0003087 to Chih-hui.

Bhullar and Nankai disclose a biosensor with a reaction catalyst comprising an enzyme.

Neither Bhullar nor Nankai disclose expressly that the reaction catalyst is a non-biocatalyst.

Chih-hui discloses the limitations of claim 15, wherein said reaction catalyst is a non-bio catalyst, such as a chemical (paragraph 0033).

Bhullar, Nankai and Chih-hui are analogous art because they are from the same field of endeavor, that is electrochemical test strips.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to utilize a non-biocatalyst as the reaction catalyst of Chih-hui in the electrochemical biosensor of Nankai because the use of a non-biocatalyst would enable the detection of more analytes, not just biological analytes. The test strip could, therefore, be used in the analysis of many different chemical species.

Therefore, it would have been obvious to combine Bhullar, Nankai and Chih-hui to obtain the invention as specified in claim 15.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar and Nankai as applied to claim 1 above, and further in view of U.S. Patent Number 6,299,757 to Feldman et al., referred to hereafter as "Feldman."

Neither Bhullar nor Nankai disclose expressly that the electrochemical biosensor contains a device activation line to automatically activate the measuring device.

Feldman discloses a biosensor with a device activation line or indicator electrode, which can activate the measuring device automatically (Col. 52, lines 14-24).

Bhullar, Nankai and Feldman are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a device activation line or indicator electrode in the electrochemical biosensor of Bhullar because such an indicator would ensure that adequate sample solution has been provided to the sample chamber for accurate and reliable measurement results, as taught by Feldman (Col. 51, lines 37-41). Automatic activation of the measuring device requires less human input so test results can be obtained faster and without the risk of operator error.

Therefore, it would have been obvious to combine Bhullar, Nankai and Feldman to obtain the invention as specified in claim 23.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nankai in view of Bhullar and U.S. Patent Number 6,309,526 to Fujiwara et al., referred to hereafter as "Fujiwara."

Regarding claim 27, Nankai discloses a method of electrochemically fabricating a biosensor (Col. 4, lines 50-51), comprising the steps of:

forming a layer of electrically conductive wires on a substrate by screen-printing (Col. 4, lines 51-57);

forming an electrode layer on top of the layer of electrically conductive wires by screen printing and drying the electrically conductive wires on the substrate and the electrode layer by heating to 100° C (Col. 4, lines 54-57 and 62-63);

forming a middle insulating layer (Col. 4, lines 57-61) with a U-shaped opening formed therein above said electrode layer of the substrate by screen printing, wherein the working electrode, the reference electrode and the auxiliary electrode are confined within the U-shaped opening and the opposing ends of said electrodes are exposed to keep contact with the measuring device (Col. 5, lines 11-16 and Fig. 4, **8**);

applying an active reaction layer on said U-shaped opening (Col. 4, line 68-Col. 5, line 5); and

adhering an upper cover with an opening formed therein above the middle insulating layer, wherein said opening is positioned at one end of said U-shaped opening (Col. 5, lines 6-16).

Nankai does not disclose expressly the screen-printed electrically conductive wires are dried before application of the electrode layer or that the method includes the step of applying a surface layer above said upper cover.

Fujiwara discloses a method of fabricating a biosensor comprising the step of forming a layer of electrically conductive wires on a substrate by screen-printing (Col. 1, lines 44-46), wherein drying time is needed after each of the steps of screen-printing (Col. 1, lines 51-55).

Bhullar discloses a method of fabricating an electrochemical biosensor comprising the step of applying a surface cover layer above an upper cover (Col. 9, lines 36-51).

Nankai, Fujiwara and Bhullar are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the step of drying the electrically conductive wires on the substrate of Fujiwara in the method of fabricating a biosensor of Nankai because such a drying step is customary in conventional screen-printing manufacturing methods, as taught by Fujiwara (Col. 1, lines 51-55). It would have been obvious to include the step of applying a surface cover layer above an upper cover of Bhullar in the method of fabricating a biosensor of Nankai because the surface cover layer blocks exposure of the reagent/sample mixture to the surrounding environment, as taught by Bhullar (Col. 5, lines 36-40). This protection from contamination would help ensure more accurate and reliable measured results.

Therefore, it would have been obvious to combine Nankai, Fujiwara and Bhullar to obtain the invention as specified in claim 27.

Nankai discloses the limitations of claim 28, wherein the middle insulating layer can be formed on top of said electrode layer by adhesion instead of screen-printing (Col. 5, lines 6-9).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nankai, Bhullar and Fujiwara as applied to claim 27 above, and further in view of Lee.

Nankai (Fig. 4, **7**, Fig. 8, **7**, Fig. 10, **7**, Fig. 12, **7** and Fig. 13, **7**) discloses a variety of shapes and configurations of the opening in the middle insulating layer.

Nankai does not disclose expressly that the opening in the middle insulating layer is T-shaped or that the transverse opening of said T-shaped opening forms two air vents on opposing sides of said biosensor.

Lee discloses a method of making an electrochemical biosensor (Col. 16, lines 38-50), wherein the opening in the middle insulating layer is T-shaped (Fig. 9B) and the

transverse opening of said T-shaped opening forms two air vents on opposing sides of said biosensor (Col. 15, line 58-Col. 16, line 5).

Nankai, Bhullar, Fujiwara and Lee are analogous art because they are from the same field of endeavor, that is electrochemical biosensors.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute the T-shaped opening in the middle insulating layer with two air vents of Lee in the electrochemical biosensor of Nankai because the T-shape sample area improves the sample application and measuring properties of the biosensor, as taught by Lee (Col. 2, lines 64-66) to ensure a quick and uniform distribution of sample (Col. 12, lines 38-40).

Therefore, it would have been obvious to combine Nankai, Bhullar, Fujiwara and Lee to obtain the invention as specified in claim 29.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Michelle Vestal whose telephone number is (571) 272-0524. The examiner can normally be reached on Monday-Friday, 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmv / RMV
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